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## **The obesity and diabetes crisis: How much bariatric surgery should be performed in the National Health Service?**

*We don't know the answer, but offering it to less than 1% of people who could benefit from it is not enough*

Richard Welbourn <sup>1</sup>, Carel le Roux <sup>2</sup>, Amanda Owen-Smith <sup>3</sup>, Sarah Wordsworth <sup>4</sup>, Jane M Blazeby <sup>5</sup>

Corresponding author [Richard.Welbourn@tst.nhs.uk](mailto:Richard.Welbourn@tst.nhs.uk)

<sup>1</sup> Consultant Surgeon, Dept Upper Gastrointestinal and Bariatric Surgery, Musgrove Park Hospital, Taunton TA1 5DA, UK

<sup>2</sup> Professor of Metabolic Medicine, Diabetes Complications Research Centre, Conway Institute, University College Dublin, Ireland

<sup>3</sup> Lecturer in Social Medicine, School of Social and Community Medicine, University of Bristol, Bristol BS8 2PR, UK

<sup>4</sup> Associate Professor of Health Economics, Nuffield Department of Population Health, University of Oxford, Oxford OX3 7AE, UK

<sup>5</sup> Professor of Surgery, Centre for Surgical Research, School of Social and Community Medicine, University of Bristol, Bristol BS8 2PR, UK

The article was conceived and written by RW. CleR, AO-S, SW and JMB reviewed and contributed to the manuscript. RW is a practising bariatric surgeon, past-

President of the British Obesity and Metabolic Surgery Society and Chair of the UK National Bariatric Surgery Registry (NBSR). The sources of information used include expert knowledge of the status of bariatric surgery in the UK and detailed knowledge of the NBSR. JMB is a practising upper gastrointestinal surgeon with expertise in methodology and randomised clinical trials. She is chief investigator of the By-Band-Sleeve study (the world's largest trial of bariatric surgery). CleR is a clinical scientist interested in obesity medicine and surgery. AO-S is a Lecturer in Medical Sociology and has extensive experience of analysing NHS rationing decisions, particularly relating to obesity surgery. SW is a health economist with expertise in economic evaluation and costing methodology. RW is the guarantor.

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## Introduction

As the epidemic of severe and complex obesity worsens, the most successful treatment, bariatric surgery, is limited in its availability – less than 1% of those who could benefit get this treatment. In contrast, victims of other life style health problems such as liver disease or car crashes related to alcohol are treated. This article explores the clinical- and cost-effectiveness of bariatric surgery and aims to estimate how many procedures the National Health Service (NHS) should perform to address the epidemic.

## Text

Bariatric surgery is the operative treatment of the stomach and upper gastrointestinal tract to facilitate weight loss. It is more effective and cost effective for the treatment of severe obesity than non-surgical measures [1]. Evidence of this is shown by 22 randomised controlled trials (RCTs) synthesized in a Cochrane review, although findings were limited to two years after surgery. Longer term data are now available for two of the included trials and a new study.[2] All favour surgery. Non-randomised data from the Swedish Obese Subjects study (SOS), a long-running cohort study of 2,000 operated patients and 2,000 matched controls, supports the RCT findings beyond the early time horizon after surgery, with weight loss being maintained for 20 years.[3] The SOS study shows that glycaemic control is improved for at least 10 years after surgery, and operated patients were more likely to go into glycaemic remission of diabetes than those having non-surgical approaches. Less progression from prediabetes to diabetes was observed.[3] In the UK a national registry of over 3,000 patients with diabetes operated on between 2011 and 2013

shows that 65% of patients previously diagnosed with diabetes had acceptable glycaemic control not requiring medication.[4] The Swedish data also indicate that in 6,000 operated patients with diabetes there was a 58% reduction in the relative risk of dying during an average of only 3.5 years follow up compared to non-operated matched patients from the registry.[5] In all the surgical series the average weight loss is 25-35% of body weight (usually at least 15kg) after 1 year for patients who are severely obese and 15-25% after 20 years. This is much greater than the average 7% weight loss achieved by patients attending intensive lifestyle weight management programmes or even using state of the art pharmacotherapy.[6, 7]

Bariatric surgery is cost effective when compared to non-surgical obesity treatments. A UK Health Technology Assessment (HTA) report which compared bariatric surgery against non-surgical options found that for patients with a body mass index (BMI) of 40 kg/m<sup>2</sup> or more, the incremental cost-effectiveness ratios (ICERs) ranged between £2,000 and £4,000 per quality adjusted life year (QALY) gained over a 20-year timescale.[9] This is well below the threshold for cost-effectiveness considered by National Institute of Health and Care Excellence (NICE) at £20,000 per QALY. For diabetic patients with a BMI of between  $\geq 30$  and  $< 40$  kg/m<sup>2</sup> this ICER reduced to £1,367 per QALY gained. Regarding maximum willingness to pay, compared with non-surgical interventions, if a decision-maker is willing to pay £20,000 for an additional QALY, then the probability of surgery being cost-effective over a 20-year time horizon was reported as 100%.[9] Few HTA reports show interventions to be so cost-effective. These low ICERs are in line with other public health interventions

such as smoking cessation and using statins for primary prevention of cardiovascular disease.[10]

In terms of a macro-level budget impact, the economic analysis for the NICE obesity update confirmed that the financial outlay for surgery was justified for the NHS.[11] In patients with diabetes for example the costs saved within three years of surgery due to reduced prescriptions recoups the initial outlay required for the intervention.[12] Recent data from the Swedish study show that the cost of diabetes drugs each year from year 1 to year 15 postoperatively is more than halved in the operated patients with diabetes compared to the non-operated group, offsetting the initial cost outlay.[13]

There are indirect cost benefits of surgery too. For example state disability allowances are reduced as a result of increased productivity if patients are subsequently able to return to paid employment.[14] This is because surgery leads to much improved activity levels: for example, the UK registry data found that only 28% of patients could climb 3 flights of stairs before surgery and this improved to over 72% 12 months later.[4] Surgery, with appropriate multi-disciplinary support during follow up, is therefore recommended to treat people who have become victims of severe and complex obesity (Box 1, Figure 1 , Figure 2). Public health measures to reduce incidence are simultaneously recommended, although we do not consider them here.

*Who is eligible for bariatric surgery?*

NICE guidance recommends that surgery is considered for individuals with severe obesity in whom all non-surgical measures have been tried but in whom adequate weight loss has not been achieved or maintained (Box 2).[10] The person must be committed to long-term follow-up and behaviour change.

#### *How many people meet the NICE criteria in the UK?*

In the UK, 1.6 million people have a BMI of at least 40 kg/m<sup>2</sup>. [15] There are at least half a million people with diabetes and other obesity-related disease with a BMI of 35 kg/m<sup>2</sup> or more, and the lowering of the NICE BMI threshold to 30 kg/m<sup>2</sup> for diabetes further increases this number to approximately 1 million. Therefore at least 2,600,000 people meet NICE criteria for surgery. [16, 17] The problem continues to escalate as an additional 60,000 people a year reach a BMI of at least 40 kg/m<sup>2</sup>. The last decade has seen a 60% increase to 3.3 million (5% of the adult population) in the number of people with type 2 diabetes and 9.5% of adults are predicted to have the condition by 2030 (190,000 new patients each year). [18, 19] Therefore without action to prevent, but also to treat these diseases, the crisis will worsen for the foreseeable future.

#### *Rates of surgery in the UK and elsewhere*

Despite obesity levels increasing, and bariatric surgery being shown to be clinically effective and cost effective, the rate of NHS bariatric procedures is falling. Between 2011/12 and 2014/15 there was a 31% reduction in the number of operations performed, from 8,794 to 6,032. [15, 20] Provision of surgery in the NHS therefore meets much less than 1% of the need. This is in stark contrast to the rates of surgery



provision per capita in many European Union countries. The UK ranks 13th out of 17 for countries where the rate is known (0.0087% of the total population or about 9/100,000), and ranks 6th for the number of operations/capita in the G8 countries even though it has the 4th largest economy.[21, 22] A European country with a similar health service, but with lower obesity rates, Sweden, spends slightly more of its gross domestic product on healthcare than the UK (9.7% vs 9.1%) yet performs 7-8 times the number of bariatric operations (70-80 procedures per 100,000 people).[23, 24] In North America the rate of surgery is around 40-50/100,000, with most of this being in the USA, as limited surgery is performed in Canada.[21]

The low rate of surgery in the UK contrasts with its high prevalence of obesity. The UK has the second highest rate of obesity in Europe, and ranks 6th internationally, with 25% of adults being obese and 62% being overweight (BMI over 25 kg/m<sup>2</sup>) or obese.[15, 25] Given the severity of the problem, the low rates of surgery despite its established benefits, and the increased number of diabetes patients eligible on the new BMI criteria, it seems urgent to consider what the potential barriers are to uptake.

#### *What are the barriers to surgery?*

The reasons appear diverse and occur at all levels (Figure 3). A key feature is that GPs are unable to refer directly to surgical services and a 'tiered' service is provided, although this is available in many parts of the country. At the population level (Tier 1), low calorie foods and exercise are recommended. Patients themselves, however, may have given up with these approaches. They may be reticent to ask for

professional help (Tier 2) because of previous negative responses from health professionals, low self-esteem or embarrassment.[26] Empathetic engagement at primary care level (Tier 2) may unintentionally promote these issues, with unsolicited advice such as 'eat less and exercise more' being harmful.[27] Although GPs receive financial incentives to measure the prevalence of obesity, there are no rewards or targets for giving treatment or referring on for specialist help. NICE estimated that about 80% of patients above the BMI thresholds would be medically and psychologically suitable for surgery. About 10% of these might wish to pursue this option.[28]

If a GP does refer for weight management this may initially be a Tier 2 community weight management programme instead of a specialist medical or surgical assessment (Tiers 3 and 4). Tier 3 is a secondary care multidisciplinary team approach. Although it is mandated that patients spend between 12 to 24 months in a Tier 3 service before referral for surgery (Tier 4), the clinics are not available widely.[29,30] The interventions offered within Tier 3 vary and outcomes are not routinely assessed. Thresholds for referral on to Tier 4 are unclear and acceptance criteria for surgery also vary between regions, based on BMI level.[20, 31] Some Tier 3 clinics mandate weight loss as a qualifying threshold for surgery although evidence for this is absent.[32,33] This prolonged pathway may create inertia and put patients off access to effective surgical treatment.[29, 31, 32]

There are no current contractual mandates to fund Tier 3 clinics and from April 2016 local commissioning groups will be free to pursue other obesity treatment strategies

if they prefer (and GPs will still not be able to refer directly to Tier 4 surgical services). Without a clear mechanism to surgery (via Tier 3 services) then access to surgery may stop.

The number of patients agreed by commissioners for surgery is also severely rationed, despite the evidence of early cost saving. This may be because it is necessarily an upfront cost, with savings being recouped in a subsequent financial year when medication costs reduce. Therefore, indicative numbers of procedures set in each region historically appear to have been determined by tokenism rather than any estimate of clinical need or benefit. Considerable patient and surgeon advocacy has not succeeded in increasing the funding available.

There also remains a popular perception amongst patients, healthcare workers and the media that surgery is high risk. This is despite Hospital Episode Statistics that show a 30-day mortality of 1.7 in 1,000 patients, lower than many more common gastrointestinal operations.[34]

Currently little is known about the effect of prejudice on provision of services. One study from the US showed that by changing the name of a bariatric clinic to one that offered 'metabolic and diabetes surgery' as opposed to 'bariatric surgery' increased the number of male patients.[35] The elephant in the room is that some healthcare workers share societal, implicit beliefs that patients with obesity are lazy and bad.[36] If encouragement to diet and exercise fails there may be an assumption that patients have not tried hard enough; they are to blame for their predicament

and do not deserve surgery. Further challenges are the either/or distinction made by some between prevention and treatment, and the strong views of those diametrically opposed to surgery. Treating a disease does not prohibit the prevention of subsequent patients developing the disease. Good examples include the widespread provision of complex and expensive treatments for other conditions caused by lifestyle issues, such as smoking related disease and road accidents, without any detriment to effective prevention programs. No healthcare worker (or member of the public) would argue that it is inappropriate to treat the victims of a car crash even if the driver was later found to be over the legal limit for alcohol – but prejudice is commonplace and blatant in bariatric/metabolic surgery (Box 1).

*Which patients should be offered surgery?*

If every patient fulfilling the NICE criteria wanted surgery it would be logistically impossible to operate on them all. Thus, a choice could reasonably be made to prioritise those with the greatest potential to have improved health outcomes to justify surgery. Operating on patients who have obesity related diseases that are expensive to treat (high direct healthcare costs), and who have a strong likelihood of reducing expensive medications afterwards, makes type 2 diabetes an obvious priority for healthcare providers. This view is strongly supported by NICE, as operating on patients with diabetes of more recent onset would lead to higher remission rates, and most prospective longitudinal studies suggest that patients with diabetes or prediabetes benefit most.[4, 11] Alternatively, given the very large number of patients in this category, priority might be given to those with established microvascular complications, as it is not controversial that many of these patients

despite best pharmacological care will progress to become more unwell while simultaneously becoming more expensive.[37] Currently it is not known whether it is more cost effective to operate on patients with more recent onset diabetes compared to those with disease of longer duration, due to the latter having greater medication costs before surgery. Another option is for the multi-disciplinary team to decide on individual need – for instance a patient with sleep apnoea falling asleep at work or needing urgent weight loss pending kidney transplant.[29]

As the rate of surgery in Sweden is static, we propose that the Swedish experience could be used as a starting point for benchmarking capacity in the NHS, where the equivalent rate of surgery is about 50,000 procedures a year for a population of 64 million (Box 3). If the operations were confined to people with a BMI of 40 kg/m<sup>2</sup> or more (1.6 million), or the 20-30% of obese type 2 diabetics with microvascular disease (0.5 million), this would still only be 3.1% or 10% of the available population, respectively. Even operating on this small proportion could make a major positive impact on patient health and improve direct healthcare expenditure within 2 years, in addition to cost savings in the future from reduced treatment costs.[13, 37]

#### *What needs to happen to increase rates of bariatric surgery?*

Based on the current evidence for the effectiveness of bariatric surgery there is a need to make it mainstream for people who have biological susceptibilities which increase their chances of becoming ‘victims’ of the modern obesogenic environment.[38] At every level of care all health workers need to leave prejudice behind, promote bariatric surgery and offer this to people who are unable to

succeed with non-operative measures. We recommend service improvement initiatives to overcome the barriers such as those used to improve cancer services. Examples might include provision of i) communication skills workshops for staff, ii) increased dietetic services, iii) investment into multi-disciplinary team working, and iv) creation of metrics to use for quality assessment with external peer review panels (as per the NHS Cancer Plan). Adopting the phrase ‘metabolic surgery’ might enable society and patients to talk about it and begin to establish a culture change.

In addition to the above recommendations, there is a need for GPs and commissioners to recognise the health benefits gained from bariatric surgery provision (and the cost savings). This will facilitate service provision. Particular concerns are the current Tier 3 and 4 services, which are often disparate. The current lack of co-ordination between these services and absence of national outcomes data from Tier 3 clinics mean that their value and role are poorly understood at present. We recommend provision of a combined Tier 3/4 service (with multi-disciplinary leadership) in surgical centres, and networks of Tier 3 services linked to Tier 4 care in a monitored and pre-agreed pathway.[27] This will mean that patients have access to surgical assessment earlier (as advocated by NICE for diabetes) and that outcomes of all interventions can be examined with teams working together to optimize care.

#### *How would the NHS cope with the extra work?*

Provision of more surgery goes hand in hand with the need for better long-term support and nutritional follow up (key to the success of surgery). Increased surgery

will therefore affect primary and secondary care. Within the UK, there is national variation in provision of surgery, with no NHS bariatric surgery being provided in Northern Ireland, and very little in Wales and Scotland.[4] In these countries we recommend that new surgical services are developed.

For most areas, however, there is a need for surgeons and GPs to re-prioritise and ensure that care for obese patients is provided and this may mean that some conditions are disinvested in (eg surgery for low risk gall stone disease, inguinal and hiatus hernias). Active development of 'obesity', or 'metabolic' care for surgical follow up in general practice could be utilised (with incentives) to improve care simultaneously for obese people not wanting surgery. It is possible that a renewed active focus on this very large group of patients will limit future costs of treating obesity and diabetes related complications.

## **Legends to figures**

Figure 1. The cost of obesity and diabetes is threatening to overwhelm healthcare systems, but prejudice against treating 'victims' of both epidemics is widespread and very few receive bariatric surgery, a clinically effective and cost saving treatment.

Figure 2. By contrast, immediate and long-term care is provided unquestioningly for car crash victims, irrespective of cause. A new paradigm in healthcare is needed to match this care for the obese.

Figure 3. Pathways and barriers to surgery and estimated numbers relevant to each stage of the system. The tiers refer to the structure of obesity care with the NHS.



**Key messages – Text box 1**

Severe and complex obesity, defined as a body mass index (BMI) of at least 40 kg/m<sup>2</sup> or a BMI of 35 kg/m<sup>2</sup> if there is obesity related disease, is a serious public health issue which requires active investment and appropriate healthcare services (Figure 1)

The perception that the condition is self-inflicted should not prohibit provision of urgent care and effective interventions such as bariatric surgery

Major surgery and support is routinely (without question) provided for victims of road traffic accidents – whatever the cause of the incident (Figure 2)

There is a need to rethink approaches to people with severe obesity and to provide urgent interventions to lead to weight loss and reduction of obesity related disease

Simultaneous (non-surgical) public health interventions are required to prevent people who are overweight and obese becoming severely obese and in need of surgery.

**Key messages – Text box 2 Summary of updated NICE Guidance CG 189 bariatric surgery recommendations (2014)**

Offer an expedited assessment for bariatric surgery to people with a BMI of 35 kg/m<sup>2</sup> or more with onset of type 2 diabetes within 10 years

Consider an assessment for bariatric surgery for people with a BMI of 30-34.9 kg/m<sup>2</sup> with onset of type 2 diabetes within 10 years

Consider an assessment for bariatric surgery for people of Asian origin with onset of type 2 diabetes at a lower BMI than other populations

Bariatric surgery is the option of choice for adults with BMI of more than 50 when other interventions have not been effective

People fitting all of the above criteria are also required to be receiving or to receive assessment in a Tier 3 specialist weight management service (or equivalent) before referral to a surgical team (Tier 4)

**Key messages – Text box 3**

Bariatric surgery associated with careful follow up is effective and cost-effective for the treatment of severe obesity and type 2 diabetes

Despite clear NICE guidance and recommendations for surgery it is provided for much less than 1% of those who could benefit from it in the UK and the rate is decreasing

Widespread variation exists in access to bariatric surgery and this affects males and minority ethnic groups

The best patient to operate on for economic return of initial outlay is unknown. It is possible that patients on multiple medications and requiring self-monitoring of blood glucose for type 2 diabetes may optimally benefit

Increasing the rate of surgery from around 6,000 to 50,000 cases per annum would bring the UK in line with other western European countries with similar healthcare systems

There is a need for close co-ordination of surgical, medical and primary care obesity services to select and support patients for surgery and provide follow up

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